



007024-000536.269687

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:)
Jean A. Chmielewski, et al.) Before the Examiner
Serial No. 10/018,043)
Filed: May 21, 2002) Group Art Unit
PHARMACEUTICAL MATERIALS AND)
METHODS FOR THEIR PREPARATION)
AND USE)

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to the duty of disclosure in accordance with 37 C.F.R. §1.56, Applicants wish to bring to the attention of the Examiner the items of information listed on the enclosed Information Disclosure Citation Form. Some of these references were brought to the attention of the Office in an International Search Report filed with the Office, GB2160100 A and EP0629393A were listed as relevant in the International Search Report. None of these references were previously listed on a form 1449A/PTO filed by the Applicant.

Information Disclosure Statement
Inventor: Jean A. Chmielewski, et al.
Application No. 10/018,043
Our Ref: 7024-536
Page 1 of 2

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:

Date of Deposit: 31 March 2004

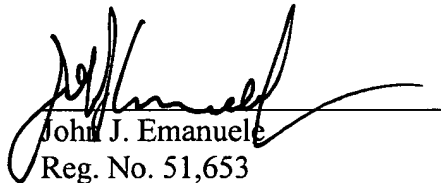
Name of Registered Representative: John J. Emanuele

Signature: 

The filing of this Information Disclosure Statement shall not be construed as an admission that the information cited is, or is considered to be, prior art or material to patentability as defined in §1.56(b).

This Statement is being submitted under 37 CFR 1.97(b) before the occurrence of one or more of the following: (a) receipt of a First Office Action on the merits, (b) passage of three (3) months from the application filing date, or passage of three (3) months from the date of entry of the national stage. Accordingly, it is believed that no fee is due. However, should any fee be required, please charge such fee to Deposit Account No. 23-3030, but not to include any payment of issue fees.

Respectfully submitted:



John J. Emanuele

Reg. No. 51,653
Woodard, Emhardt, Moriarty,
McNett & Henry, LLP
Bank One Center Tower
111 Monument Circle, Suite 3700
Indianapolis, Indiana 46204-5137
(317) 634-3456

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher city and/or country where published	T ²
		BEAVIS, Ronald C. et al. Epitaxial Protein Inclusion in Sinapic Acid Crystals, J. Phys. D: Appl. Phys. 26 (1993) 442-447.	
		BORMAN, Stu. Biochemical Applications of Mass Spectrometry Take Flight, C&EN, June 19, 1995, 23-32.	
		CARPENTER, J.F. and CROWE, J.H. Infrared Spectroscopic Studies of the Interaction of Carbohydrates with Dried Proteins, Biochemistry, 1989, pp. 3916-22, Vol. 28.	
		CARPENTER, J.F. et al. Separation of Freezing- and Drying-induced Denaturation of Lyophilized Proteins by stress-specific stabilization: I. Enzyme Activity and Calorimetric Studies. Arch. Biochem. Biophys., 1993, pp. 456-64, Vol. 303.	
		CHMIELEWSKI, Jean, et al. Single-Crystal Matrix Isolation of Biopolymers, J. Am. Chem. Soc., 10/29/97, pp. 10565-66, Vol. 119, No. 43.	
		GOKE, R., et al. Exendin-4 is a High Potency Agonist and Truncated Exendin-(9-39)-amide an Antagonist at the Glucagon-like Peptide 1-(7-36)-amide Receptor of Insulin-secreting Beta-cells. J. Biol. Chem., 9/15/93, pp. 19650-55, 268 (26).	
		HILLENKAMP, Franz, et al. Matrix-Assisted Laser Desorption/Ionization Mass Spectrometry of Biopolymers, Analytical Chemistry, 12/15/91, pp. 1193A-1283A, Vol. 63, No. 24.	
		IZUTSU, K., et al. The Effects of additives on the stability of freeze-dried β -galactosidase stored at elevated temperatures. Int. J. Pharm., 1991, pp. 137-46, Vol. 71.	
		IZUTSU, K., et al. Decreased protein-stabilizing effects of cryoprotectants due to crystallization. Pharm. Res., 1993, pp. 1232-37, Vol. 10.	
		KURIMOTO, Miki et al. Kinetic Stabilization of Biopolymers in Single-Crystal Hosts: Green Fluorescent Protein in α -Lactose Monohydrate, J. Am. Chem. Soc. 1999, Vol. 121, pp. 6952-6953.	
		MALKIN, A.J. et al. Mechanisms of Growth for Protein and Virus Crystals, Nature Structural Biology, Vol. 2, No. 11, November, 1995.	
		POWERS, H.E.C. Sucrose Crystals: Inclusions and Structure, Sugar Technol Rev., I (1969/70) 85-190	
		RASIMAS, J.P. et al. Measuring Self-Assembly in Solution: Incorporation and Dynamics of A "Tailor-Made Impurity" in Precrystalline Glucose Aggregates, Department of Chemistry and Department of Chemical Engineering, Michigan State University, East Lansing, Michigan.	
		STRUPAT, K. et al. 2,5-Dihydroxybenzoic Acid: A New Matrix For Laser Desorption-Ionization Mass Spectrometry, International Journal of Mass Spectrometry and Ion Processes, 111 (1991) 89-102	
		VISSER, R.A., et al. A Natural Crystal Growth Retarder in Lactose. Milk Diary J., 1980, pp. 255-75, Vol. 34.	
		WINDHOLZ, M. (editor). Merck Index, 10 th edition, p. 769.	